

Animal and Plant Health Inspection Service, USDA

§ 123.1

which have been exposed to any such disease.

(f) *Permittee*. A person who resides in the United States or operates a business establishment within the United States, to whom a permit to import or transport organisms or vectors has been issued under the regulations.

(g) *Person*. Any individual, firm, partnership, corporation, company, society, association, or other organized group of any of the foregoing, or any agent, officer, or employee of any thereof.

[31 FR 81, Jan. 5, 1966, as amended at 57 FR 30899, July 13, 1992]

§ 122.2 Permits required.

No organisms or vectors shall be imported into the United States or transported from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia without a permit issued by the Secretary and in compliance with the terms thereof: *Provided*, That no permit shall be required under this section for importation of organisms for which an import permit has been issued pursuant to part 102 of this subchapter or for transportation of organisms produced at establishments licensed under part 102 of this subchapter. As a condition of issuance of permits under this section, the permittee shall agree in writing to observe the safeguards prescribed by the Administrator for public protection with respect to the particular importation or transportation.

(Approved by the Office of Management and Budget under control number 0579-0015)

[28 FR 7896, Aug. 2, 1963. Redesignated at 31 FR 81, Jan. 5, 1966 and amended at 48 FR 57473, Dec. 30, 1983; 57 FR 30899, July 13, 1992; 59 FR 67134, Dec. 29, 1994]

§ 122.3 Application for permits.

The Secretary may issue, at his discretion, a permit as specified in § 122.2 when proper safeguards are set up as provided in § 122.2 to protect the public. Application for such a permit shall be made in advance of shipment, and each permit shall specify the name and address of the consignee, the true name and character of each of the organisms

or vectors involved, and the use to which each will be put.

(Approved by the Office of Management and Budget under control number 0579-0015)

[23 FR 10065, Dec. 23, 1958. Redesignated at 31 FR 81, Jan. 5, 1966 and amended at 48 FR 57473, Dec. 30, 1983; 59 FR 67134, Dec. 29, 1994]

§ 122.4 Suspension or revocation of permits.

(a) Any permit for the importation or transportation of organisms or vectors issued under this part may be formally suspended or revoked after opportunity for hearing has been accorded the permittee, as provided in part 123 of this subchapter, if the Secretary finds that the permittee has failed to observe the safeguards and instructions prescribed by the Administrator with respect to the particular importation or transportation or that such importation or transportation for any other reason may result in the introduction or dissemination from a foreign country into the United States, or from one State, Territory or the District of Columbia to another, of the contagion of any contagious, infectious or communicable disease of animals (including poultry).

(b) In cases of wilfulness or where the public health, interest or safety so requires, however, the Secretary may without hearing informally suspend such a permit upon the grounds set forth in paragraph (a) of this section, pending determination of formal proceedings under part 123 of this subchapter for suspension or revocation of the permit.

[23 FR 10065, Dec. 23, 1958. Redesignated at 31 FR 81, Jan. 5, 1966, and amended at 57 FR 30899, July 13, 1992]

PART 123—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE VIRUS-SERUM-TOXIN ACT

AUTHORITY: 21 U.S.C. 111 and 151-159; 7 CFR 2.22, 2.80, and 371.4.

§ 123.1 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the Department of Agriculture promulgated in subpart H of part 1, subtitle A,

title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings under the Virus-Serum-Toxin Act.

[42 FR 10960, Feb. 25, 1977]

PART 124—PATENT TERM RESTORATION

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AUTHORITY: 35 U.S.C. 156; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 58 FR 11369, Feb. 25, 1993, unless otherwise noted.

Subpart A—General Provisions

§ 124.1 Scope.

(a) This part sets forth procedures and requirements for APHIS review of applications for the extension of the term of certain patents for veterinary biological products pursuant to 35 U.S.C. 156—Extension of patent term. Responsibilities of APHIS include:

(1) Assisting PTO in determining eligibility for patent term restoration;

(2) Determining the length of a product's regulatory review period;

(3) If petitioned, reviewing and ruling on due diligence challenges to APHIS's regulatory review period determinations; and

(4) Conducting hearings to review initial APHIS findings on due diligence challenges.

(b) The regulations in this part are designed to be used in conjunction with regulations issued by PTO concerning patent term extension which may be found at 37 CFR 1.710 through 1.791.

[58 FR 11369, Feb. 25, 1993, as amended at 64 FR 43045, Aug. 9, 1999]

§ 124.2 Definitions.

Animal and Plant Health Inspection Service (APHIS). The agency in the Department of Agriculture responsible for licensing veterinary biological products under the Virus-Serum-Toxin Act.

Applicant. Any person who submits an application or an amendment or supplement to an application under 35 U.S.C. 156 seeking extension of the term of a patent.

Due diligence petition. A petition submitted under § 124.30 of this part.

Informal hearing. A hearing which is not subject to the provisions of 5 U.S.C. 554, 556, and 557 and which is conducted as provided in 21 U.S.C. 321(y).

License applicant. Any person who, in accordance with part 102 of this chapter, submits an application to the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture for a U.S. Veterinary Biological Product License.

Patent. A patent issued by the Patent and Trademark Office of the United States Department of Commerce.

Person. Any individual, firm, partnership, corporation, company, association, educational institution, State or local government agency, or other organized group of any of the foregoing, or any agent, officer, or employee of any thereof.

PTO. The Patent and Trademark Office of the United States Department of Commerce.

Subpart B—Eligibility Assistance

§ 124.10 APHIS liaison with PTO.

Upon receipt of a copy of an application for extension of the term of a veterinary biologic patent from PTO,